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NASA Policy Directive

NPD 7100.8E

Effective Date: May 31, 2002

Expiration Date: June 14, 2012

COMPLIANCE IS MANDATORY[Printable Format \(PDF\)](#)

Request Notification of Change

(NASA Only)

Subject: Protection of Human Research Subjects (Revalidated with admin. changes 6/14/2007)

Responsible Office: Office of the Chief Health & Medical Officer

1. POLICY

a. This NPD sets forth NASA's policies for the protection of human research subjects, which is of primary importance in the conduct of any human research. All human research conducted, or supported by NASA, whether on the ground, in aircraft, or in space, will follow the provisions of NASA regulations contained in 14 CFR Part 1230 and Department of Health and Human Services (HHS) regulations contained in 45 CFR Part 46.

b. The authorized NASA official for the protection of human subjects is the Chief Health and Medical Officer (CHMO), NASA Headquarters. All human research, funded, sponsored, conducted, or supported by NASA, will be reviewed by an Institutional Review Board (IRB), approved by NASA or the Office of Human Research Protection (OHRP) at HHS. IRB's will be established at NASA Centers to review all ground-based and aeronautical flight research, involving human subjects, that is conducted at the Centers or which utilizes NASA Center, equipment, or personnel. All research performed on NASA spacecraft, involving crewmembers, will be reviewed by the IRB at the Johnson Space Center (JSC).

c. The IRB has authority to approve, disapprove, or require changes in the proposed human research protocols and procedures and to suspend or terminate its approval of research activities that are not conducted in accordance with the approved protocol or that have been associated with serious harm to subjects.

d. No Principal Investigator (PI) may involve a human being as a subject in research covered by this policy, unless the written informed consent of the subject or the subject's legally authorized representative has been obtained. Such consent shall be sought only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. No informed consent, whether oral or written, may include

any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or which releases or appears to release the PI, the sponsor, the institution, or its agents from liability for negligence.

The conditions under which an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or under which an IRB may waive the requirements to obtain informed consent, must include all of the following elements, which must be documented by the IRB:

- (1) The research involves no more than minimal risk;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration;
- (4) Whenever appropriate, the subjects shall be provided with additional pertinent information after participation; and
- (5) Astronaut and other human experimental data derived from, or associated with such approved research, must be nonattributable to any individual.

e. All classified human research must have informed consent of the subjects.

f. All institutions proposing human research, funded by NASA, shall be required to give written assurance, as provided in 14 CFR 1230.103, to the authorized NASA official. An OHRP-approved assurance of compliance with the HHS regulations (45 CFR 46.103) for the protection of human subjects will satisfy this requirement. Assurances from institutions for projects utilizing NASA facilities, equipment, or personnel will not be accepted; NASA IRB review and approval shall be obtained. NASA Centers conducting human research or studies shall file Multiple Project Assurance's (MPA) with the authorized NASA official every 5 years and submit an annual report on the research and IRB activities. NASA Centers not conducting human research or studies will file a letter with supporting documentation certifying this fact to the authorized NASA official every year.

g. When research covered by this policy takes place in foreign institutions, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. Studies funded or sponsored by NASA must follow this NPD. In these circumstances, if NASA determines that the procedures prescribed by the foreign institution afford protections that are greater than those provided in this policy, the Agency may approve the use of the foreign procedures in addition to the procedural requirements provided in this policy, in accordance with 14 CFR Part 1230.101 (h) and 45 CFR 46.101 (h).

h. PI's are required to familiarize themselves with Agency and Center policies and procedures for the conduct of human research. Any NASA PI or a PI supported by NASA involved in human research, who does not comply with the policies and procedures of this NPD or with the protocol as approved, may have his or her research immediately suspended or terminated when such noncompliance becomes known to the appropriate IRB, NASA Center Director, Associate Administrator of the Office of Exploration Systems Mission Directorate, Office of the Associate Administrator space Operations Mission Directorate, or the CHMO. Evidence of noncompliance may be cause for the application of sanctions.

2. APPLICABILITY

- a. This NPD applies to NASA Headquarters and all NASA Centers, including Component Facilities, and will be followed by all members of the research teams in all research experiments involving human subjects that are funded or sponsored by NASA or conducted in NASA facilities, aircraft, or spacecraft.
- b. All human research conducted under a cooperative or reimbursable arrangement or agreement entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity must also comply with the terms and conditions of this NPD.
- c. Research activities, involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, are exempted from this NPD, if these sources are publicly available, or if its information is recorded in such a manner that subjects cannot be identified directly or through identifier links to the subjects.

3. AUTHORITY

- a. 42 U.S.C. 2473 (c)(1), Section 203 (c)(1), The National Aeronautics and Space Act of 1958, as amended.
- b. 14 CFR Part 1230 and 45 CFR Part 46, Protection of Human Subjects.

4. APPLICABLE DOCUMENTS

World Medical Association Declaration of Helsinki adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; and the 41st World Medical Assembly, Hong Kong, China, September 1989.

5. RESPONSIBILITY

- a. The authorized NASA official for the protection of human subjects is the CHMO, NASA Headquarters.
- b. The authorized NASA official is responsible for ensuring that the written institutional assurances related to NASA-supported human research, NASA Center MPA's, and any NASA Center letters certifying that human research or studies are not being conducted at the Center, are filed in a timely manner with NASA Headquarters. All or part of the authority may be redelegated, without power of further redelegation, to a senior NASA Headquarters employee, usually the Deputy CHMO, who reports to the authorized NASA official.
- c. The authorized NASA official is responsible for ensuring that the Administrator, the appropriate Mission Directorate Associate Administrator, the Office of Safety and Mission Assurance, the NASA General Counsel, and the NASA Inspector General (when appropriate) are kept fully and currently informed, through official channels, of significant actions, problems, or other matters of substance related to the exercise of this authority.
- d. The NASA Center Directors are responsible for implementing this NPD within their assigned areas of responsibility. The Center Directors are responsible for ensuring that

the written institutional assurances related to Center-supported human research, Center MPA's, and any NASA Center letters certifying that human research or studies are not being conducted at the Center, are filed in a timely manner with the authorized NASA official. In addition, the Center Directors are responsible for establishing an IRB at their respective Centers to review all ground-based, aeronautical, and aerospace flight research, involving human subjects, that is conducted at their Center.

e. All research involving human subjects, including flight crews, which is performed in NASA spacecraft will be reviewed by the IRB at the JSC. The NASA Flight IRB will be appointed by the CHMO. In addition, flight surgeons are responsible for monitoring the health of the crew during the conduct of research protocols and assessing the crewmember's continued suitability as a subject.

f. The primary responsibility of the IRB is to protect the rights of and ensure the health and safety of every person who is a subject of any research in NASA facilities, including NASA aircraft or spacecraft, or is a subject of NASA-funded or NASA-sponsored research. Specifically, the IRB's are responsible for the following:

(1) Approving, disapproving, or requiring changes in the proposed human research protocols and procedures;

(2) Ensuring that the human subjects have given informed consent and reviewing such informed consent, or documenting the reasons and safeguards in all cases where the informed consent procedure, or any element of such procedure, has been altered or waived; and

(3) Suspending or terminating approval of research activities that are not being conducted in accordance with the approved protocol or that have been associated with serious harm to subjects.

g. All PI's are responsible for complying with Agency and Center policies and procedures for the conduct of human research.

h. The CHMO will represent NASA in all forums with the external community, including in part, with other Federal Agencies and international partners, on protection of human subject matters.

6. DELEGATION OF AUTHORITY

None.

7. MEASUREMENTS/VERIFICATION

Measurements of Agency compliance with this policy for the protection of human subjects in NASA research are contained in the attachment.

8. CANCELLATION

NPD 7100.8D, Protection of Human Research Subjects, dated May 31, 2002.

**Revalidated June 14, 2007, Original signed by: /s/ Sean O'Keefe
Administrator**

ATTACHMENT A: (TEXT)

Metrics or measurements of Agency compliance with this policy for the protection of human subjects in NASA research are the following:

- (1) Percentage of NASA Centers with active MPA and certifying letters on file with the authorized NASA official;
- (2) Percentage of NASA Centers filing timely MPA's or certifying letters;
- (3) Number of research proposals reviewed by IRB's;
- (4) Number of research proposals approved by IRB's;
- (5) Number of complaints to IRB's;
- (6) Timeliness of response to complaints, including Headquarters notifications;
- (7) Number and type of sanctions imposed; and
- (8) Number of audits conducted and corrective measures adopted.

Appendix: Astronaut Health Care and Biomedical Research Supplemental Guidance to NPD 8900.1G and NPD 7100.X (E)

PURPOSE:

This Appendix sets forth guidelines for bridging the policies on NPD 8900.1G, Astronaut Medical and Dental Observation, Study and Care Program, and NPD 7100.8E, Protection of Human Research Subjects, when both apply simultaneously during the performance of an astronaut's duties.

These guidelines address the multiplicity of issues surrounding the medical support of astronauts and of the NASA-supported space crews as well as their participation in biomedical research as research subjects. They provide guidance and direction in the ethical practice of medical care and conduct of human research in support of space missions.

POLICY:

a. Medical support of astronauts and of the NASA-supported space crews prior to spaceflight, while in space, and after spaceflight is guided by practices established or approved by the Medical Policy Board and/or the CHMO includes the application of approved countermeasures. Medical management is the responsibility of the attending flight surgeon. Basic medical monitoring, countermeasures, and clinical treatment protocols, and their frequency will be independently evaluated periodically by an expert team reporting to the Medical Policy Board and CHMO. This evaluation will assess the actual risk, benefit, and value of treatments.

This medical support plan and requirements should be based on--

- (i) evidence-based knowledge of physiological responses to spaceflight;
- (ii) knowledge of the specific mission scenario and crewmember's activities timeline;
- (iii) knowledge of the specific, all-inclusive research protocol in which the crewmember

participates as a research subject and the research protocol timelines;

(iv) monitoring of select environmental parameters and their changes, for possible interactions with the research protocols, countermeasures or medical monitoring or treatment.

Flight surgeons are responsible for--

(i) monitoring the health of the crew during the conduct of research protocols and assessing the crewmember's continued suitability as a subject;

(ii) remaining cognizant of the particular experimental research outcomes when they are reported, after the flight is completed;

(iii) developing and continuously updating requirements for operational clinical research.

b. Biomedical Research:

Biomedical Research is designed to--

(i) develop the understanding of the mechanisms underlying the changes during and after spaceflight;

(ii) design, evaluate, and validate appropriate countermeasures and rehabilitation procedures based on the knowledge from (i);

(iii) provide the pathophysiological evidence required for safe and effective medical care in space and after flight.

All monitoring or testing other than that essential to medical care and health maintenance of astronauts and the NASA-supported space crews should be considered biomedical research in that it is presumed that a hypothesis has been formulated, that similar procedures or data are required from more than one subject, and the proposal was designed in a scientifically valid manner.

All research will be independently peer reviewed. All flight experimental research conducted concurrently on the same crewmember will be integrated into a single protocol and will be reviewed by the IRB at the JSC for risk, taking into account interactions with mission activities, environmental data, and medical care activities.

c. Coordination of Medical Care and Biomedical Research:

This Appendix is designed to ensure full integration of methods to foster a commitment among the astronaut corps, the NASA-supported space crews, the flight surgeons, and the research community to define and optimize biomedical operational and research objectives for each flight mission or Space Station operation. The Space and Life Sciences Directorate at JSC will be responsible for ensuring this integration.

(i) Research protocols and health care monitoring requirements will be coordinated, when possible, into a single activity and timeline to avoid duplication and unnecessary interference with the crewmember.

(ii) Mission timelines and research protocols will be planned in coordination with the medical operational activities to minimize impact on health and safety of crewmembers and ensure integrity of research data.

(iii) Research data obtained from astronauts is not to be used for medical or flight

certification purposes. It may be available as background information to be used when required for medical care or for medical emergency purposes during and after flight.

(iv) The following guidance applies:

Before a researcher has access to medical data, a crewmember's informed consent and an assurance of confidentiality will be required to be on file in order to preclude the inappropriate release or use of any medical data.

Investigators should identify in their proposals and revise as necessary, prior to the mission, applicable health, environmental, or mission activities data that might impact the research protocol(s). Applicable deviations in the mission profiles and appropriate data will be reported to the PI in a timely fashion to ensure research integrity.

Research data will not be presented or published in any way that allows identification of the participating crewmember or other subjects without their explicit written consent(s).

d. Bioethics of crewmembers volunteering as research subjects.

(i) Prior to selection as astronauts, applicants should be provided with information to ensure that they understand that they will be asked to volunteer to participate as research subjects during the course of their employment with NASA. Additionally, they should be informed that, as research subjects, they have certain rights, including the right to refuse to participate and the right to withdraw from participation. This information should be presented fairly and objectively to avoid real or perceived coercion.

(ii) Informed consent and consent forms should be comprehensive and in simple, layman's language and should also address the purpose of the research and the disposition of the data. Research subjects can withdraw consent at any time, including after the commencement of the research.

(iii) Potential crew members expected to volunteer as human subjects will receive an in-depth briefing of all biomedical experiments, including attendant risks and integrated risks, to obtain informed consent for participation prior to assignment as a crewmember to that flight.

(iv) Data and results from the research and their significance should be appropriately briefed to the participating crewmembers before publication in the open literature.

(v) Periodic informational and educational briefings on major biomedical findings and their implications from space missions will be provided by the PI or life sciences research personnel to the astronaut corps.

e. Effective date: This guidance is effective with the date of issuance and the signature of the Chief Health and Medical Officer, NASA.

/s/ Richard S. Williams, M.D., FACS, Date 6/1/2007

(URL for Graphic)

Attached_URL

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